investigational human drug products for use in the treatment of neurologic diseases.

The topics considered by the Peripheral and Central Nervous System Drugs Advisory Committee require specialized expertise in the practice of neurology, pediatric neurology, epidemiology, statistics, and other related specialties that is not within the primary scope of other FDA advisory committees. Potential topics that may need committee input include products related to the topics outlined in Section (6) below. These and other issues cannot be appropriately addressed by another standing committee without diminishing the depth and relevance of the expert input provided to the Agency.

6. If the consultation is a committee renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue:

Summary of Previous Accomplishments:

In 2024, the Peripheral and Central Nervous System Drugs Advisory Committee held one meeting:

June 10, 2024: Discuss biologics license application 761248, for donanemab solution for intravenous infusion, submitted by Eli Lilly and Co., for the treatment of early symptomatic Alzheimer's disease.

In 2023, the Peripheral and Central Nervous System Drugs Advisory Committee held three meetings:

March 22, 2023: Discussed new drug application (NDA) 215887, for tofersen (BIIB067) intrathecal injection, submitted by Biogen Inc., for the treatment of amyotrophic lateral sclerosis (ALS) associated with a mutation in the superoxide dismutase 1 (SOD1) gene.

April 14, 2023 (joint meeting with the Psychopharmacologic Drugs Advisory Committee): Discussed supplemental new drug application (sNDA) 205422 s009, efficacy supplement for REXULTI (brexpiprazole) tablets, submitted by Otsuka Pharmaceutical Company, Ltd., and Lundbeck, Inc., for the proposed treatment of agitation associated with Alzheimer's dementia.

June 9, 2023: Discussed supplemental biologics license application (sBLA) 761269/s–001, for LEQEMBI (lecanemab) solution for intravenous infusion, submitted by Eisai, Inc., for the treatment of Alzheimer's disease, initiated in patients with mild cognitive impairment or mild dementia stage of disease.

7. Explanation of why the committee/subcommittee is essential to the conduct of agency business:

The Committee plays a critical role in enabling FDA to meet the requirements of section 505(n)(1) and (s)(1) of the Federal Food, Drug, and Cosmetic Act by providing expert scientific advice and recommendations. The Peripheral and Central Nervous System Drugs Advisory Committee is the only FDA advisory committee that provides specialized expertise in neurology, pediatric neurology, epidemiology, statistics, and other related specialties. Without the Peripheral and Central Nervous System Drugs Advisory Committee, FDA's ability to obtain external input on issues related to the approval and regulation of neurological products would be significantly limited.

In conclusion, this public interest determination documents that reestablishing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14829 Filed 7–22–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people living with the disease and their caregivers. During the third meeting of 2026, the Advisory Council will hear from a panel organized by the research subcommittee; updates from federal agencies, including an overview of the authorities of the National Institutes of Health, the Food and Drug Administration, and the Centers for Medicare & Medicaid Services; legislative updates from advocacy groups; and an update on the Robotic-Enabled Microsurgical Intervention for Neurodegenerative Disease (REMIND) Study. Advisory Council subcommittees will also present their recommendations for adoption by the full Advisory Council.

DATES: The meeting will be held on Monday, August 3, 2026, from 10:00 a.m. to 5:00 p.m.

ADDRESSES: The meeting will be a hybrid of in-person and virtual and will be held in the Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. It will also stream live at *www.hhs.gov/live*.

FOR FURTHER INFORMATION CONTACT: Maria-Theresa Okafor, 771–223–7102, *maria-theresa.okafor@hhs.gov*. Note: The meeting will be available to the public live at *www.hhs.gov/live*.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: Alzheimer's disease and related dementias, research and innovation, legislative updates, and council recommendations.

Procedure and Agenda: The meeting will be webcast at *www.hhs.gov/live* and video recordings will be added to the National Alzheimer's Project Act website [1] when available after the meeting. This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. Participants joining in person should note that seating may be limited. Those wishing to attend the meeting in person must send an email to *napa@hhs.gov* and put ''August Meeting Attendance'' in the subject line by Monday, July 27 so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email. Please note that individuals entering HHS owned, leased, or operated facilities must present a REAL ID compliant credential or another federally approved form of identification. Below is the list of acceptable forms of ID.

- State-issued Enhanced Driver's License.
- U.S. passport.[2]
- U.S. passport card.[3]
- DHS trusted traveler cards (Global Entry, NEXUS, SENTRI, FAST).
- U.S. Department of Defense ID, including IDs issued to dependents.
- Permanent resident card.
- Border crossing card.

[1] *https://aspe.hhs.gov/collaborations-committees-advisory-groups/napa*

[2] *https://travel.state.gov/content/travel/en/passports.html.*

[3] *https://travel.state.gov/content/travel/en/passports/need-passport/card.html.*

• An acceptable photo ID issued by a federally recognized [4] Tribal Nation/Indian Tribe, including Enhanced Tribal Cards (ETCs).
• HSPD–12 PIV card.
• Foreign government-issued passport.
• Canadian provincial driver's license or Indian and Northern Affairs Canada card.
• Transportation worker identification credential.
• U.S. Citizenship and Immigration Services Employment Authorization Card (I–766).
• U.S. Merchant Mariner Credential.
• Veteran Health Identification Card (VHIC).

Comments: Time is allocated on the agenda to hear public comments from 4:35 p.m. to 5:00 p.m. The time for oral comments will be limited to two (2) minutes per individual. To provide a public comment, please register by emailing your name to *napa@hhs.gov* by Monday, July 27, 2026. Registered commenters will receive both a dial-in number and a link to join the meeting virtually; individuals will have the choice to either join virtually via the link, or to call in only by using the dial-in number. *Note:* There may be a 30–45 second delay in the livestream video presentation of the conference. For this reason, if you have pre-registered to submit a public comment, it is important to connect to the meeting by 4:20 p.m. to ensure that you do not miss your name and allotted time when called. If you miss your name and allotted time to speak, you may not be able to make your public comment. Public commenters will not be admitted to the virtual meeting before 4:05 p.m. but are encouraged to watch the meeting at *www.hhs.gov/live.* Should you have questions during the session, please email *napa@hhs.gov* and someone will respond to your message as quickly as possible.

• To ensure accuracy, please submit a written copy of oral comments for the record by emailing *napa@hhs.gov* by Wednesday, August 5, 2026. These comments will be shared on the website and reflected in the meeting minutes.

• In lieu of oral comments, formal written comments may be submitted for the record by Wednesday, August 5, 2026, to Maria-Theresa Okafor, Ph.D., MCG, OASPE, 200 Independence Avenue SW, Room 438F.7, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Cynthia L. Goss,

Deputy Assistant Secretary for Planning and Evaluation (Health Policy), Performing the Delegable Duties of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2026–14907 Filed 7–22–26; 8:45 am]

BILLING CODE 4150–28–P

[4] *https://www.federalregister.gov/documents/2021/01/29/2021-01606/indian-entities-recognized-by-and-eligible-to-receive-services-from-the-united-states-bureau-of.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: RXFP1 AGONISTS

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Center for Advancing Translational Sciences, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this Notice to Modala Bio, Inc. (Modala), headquartered in Delaware.

DATES: Only written comments and/or applications for a license which are received by the National Center for Advancing Translational Sciences' Office of Strategic Alliances on or before August 24, 2026 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Jasmine Kalsi, M.S., Licensing and Patenting Manager, Office of Strategic Alliances, Telephone: 301–435–0129; Email: *jasmine.kalsi@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

''RXFP1 AGONISTS''

(1) U.S. Provisional Application No. 63/780,976 and NIH Reference No.: E–145–2024–0–US–02 filed 31 March 2025.

(2) U.S. PCT Application No. PCT/US2026/021648, filed March 31, 2026, and NIH Reference No.: E–145–2024–0–PC–01.

The patent rights in these inventions have been either assigned and/or exclusively licensed to the government of the United States of America, Florida International University (FIU), and University of South Florida (USF).

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

''NCGC00846044, TRND00589605, TRND00600099 and TRND00658394, including any related analogs for the treatment or prevention of: cancers, cardiovascular, pulmonary, and fibrotic diseases.''

The present invention is directed to novel relaxin receptor (RXFP1 receptor) small molecule agonists useful for treating relaxin-related disorders including fibrosis, certain cancers, vascular calcifications, including atherosclerosis, and heart failure. The RXFP1 agonists of this invention possess a number of advantages not found in earlier RXFP1 agonists. These properties include, for example, improved bioavailability, low toxicity, and better activity in RXFP1-dependent biological functional assays.

The development of small-molecule agonists of RXFP1 would have numerous benefits and will allow investigating additional therapeutic applications where chronic administration is required. NCATS has identified a series of small-molecule agonists of RXFP1 which are potent, highly selective, easy to synthesize, and with reasonable metabolic and physical properties. The molecules of this invention display similar efficacy as the natural hormone in several functional assays. Mutagenesis studies have mapped the specific regions responsible for relaxin receptor activation by these compounds to an allosteric site on the receptor. Finally, these compounds display good in vivo pharmacokinetic properties and are currently being evaluated in vivo.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within thirty (30) days from the date of this published Notice, the National Center for Advancing Translational Sciences receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than